# "I Can Help You If You Would Just Let Me!": The Journey From Vendor to Trusted Partner An Interview with Demetrius Carter

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Successful vendor–sponsor relationships, such as those between a contract research organization (CRO) and pharmaceutical company, assure and accelerate regulatory success for new products. Often, however, this relationship fails, which delays approval and, in turn, costs the pharmaceutical company money by shortening the market time of the product.

Demetrius Carter, MBA, PMP, RAC-US, shared insight on this relationship at the AMWA Carolinas 2021 Spring Conference by providing methods of assuring and accelerating regulatory success for pharmaceutical companies, reasons that CRO–pharmaceutical company relationships fail, successful mitigation strategies, case studies illustrating failed relationships, and, finally, techniques to strengthen and transform the CRO–pharmaceutical company relationship into a strategic partnership.

Mr Carter is a clinical development executive with over 20 years of drug development experience in the pharmaceutical and medical device industries. He is the Senior Vice President for Regulatory Services at Certara Synchrogenix, where he is responsible for their Regulatory Writing, Strategy, and Operations teams. His presentation was entitled "'I Can Help You if You Would Just Let Me!': Best Practices in Overcoming a Challenging Sponsor."[1]

**AMWA:** ***How Can CROs Assure and Accelerate Regulatory Success for Pharmaceutical Companies?***

**Carter:** To assure and accelerate regulatory success for pharmaceutical companies, 5 key components of the CRO's regulatory process must be fully established and supported by the following key CRO personnel and advanced technology.

*Regulatory and Medical Writing*

Writers should be experienced at producing all document types for major regulatory agencies by using the Common Technical Document (CTD) format. Technologies used by writers should drive efficiency and accuracy and speed the time to document completion. This should produce high-quality documents that are properly managed across the document development life cycle.

*Regulatory Consulting and Regulatory Affairs*

There should be a robust drug development strategy to guide document development. This should include a clear submission strategy directed by effective leadership, a gap analysis to detect and provide solutions to inadequacies, and expedited pathways to advance urgent documents. This should be an integrated global strategy so that content from the primary submission can be reused for submission to multiple regulatory markets.

*Regulatory Operations*

The CRO should be an expert at submitting regulatory documents by using advanced technology that is compliant with global health authorities. This expertise should include a simplified submission review, proactive management of timelines and deliverables, and electronic CTD delivery for every therapeutic area.

*Regulatory Technology*

To save time and resources, the CRO should use advanced technology powered by artificial intelligence (AI) to map clinical data to templates and automate development of documents.

*Transparency and Disclosure*

CROs should meet and exceed compliance requirements by providing services such as data anonymization and redaction powered by AI, clinical trial postings and result disclosure, plain language summaries, and strategies to promote patient engagement.

Although the outlined approach may be ideal for large CROs, smaller organizations may not have the financial resources to establish all 5 components. For example, significant technology investments may be too costly for small CROs. In this situation, these organizations may choose to focus on achieving operational excellence and raising their profile through consistent and high-quality delivery of their medical writing and regulatory affairs services.

**AMWA:** ***What Are Some Primary Reasons for a Failed CRO–Pharmaceutical Company Relationship?***

**Carter:** Some of the primary reasons for a failed CRO–pharmaceutical company relationship include failing to deliver the document by the agreed upon timeline, delivering a document of poor quality that does not meet expectations or industry standards, missing a return on investment when the cost of services for the deliverable does not match the pharmaceutical company's perceived value, and a failure to address ongoing performance concerns within the relationship.

**AMWA:** ***How Can CROs Show Their Value to Pharmaceutical Companies?***

**Carter:** By developing a unique value proposition (UVP). This will describe the benefits the CRO can provide, and what makes these benefits valuable to the pharmaceutical company. The UVP should be focused and easy to articulate. For this to occur, the CRO must understand the pharmaceutical company's challenges and describe how the CRO's service will address those challenges. The CRO must also present key differentiators that distinguish its services from those of other CROs and describe the key benefits it brings to the table. Finally, the CRO must craft a message that demonstrates the value of their solution to the pharmaceutical company.

**AMWA:** ***How Can Writers Improve Their UVP?***

**Carter:** To improve their UVP, writers should regularly review and reflect upon their performance by using a 360-degree review process that includes a self-evaluation. In addition, writers should choose 1 to 2 areas to improve upon annually, such as technical skills, knowledge, abilities, or competencies. A writer should compare the quality of the services provided with the fee the writer charges. This fee should be commensurate with the writer's experience and the service provided. Finally, writers should find opportunities to innovate, such as the use of technology to improve the quality and efficacy of their documents.

In the book, *Good to Great*, Jim Collins describes the Hedgehog Concept.[2] This concept is based upon understanding the intersection of 3 circles (Figure 1). When using these circles, writers should consider

1. Passion. To be the best, writers should only focus on activities they can be passionate about.
2. Excellence. Being good at something is not enough. Writers must understand what they can excel at to truly be great.
3. Drive. Know what activities drive consistent and reliable capital and profitability.

All 3 circles are required to transition from being good to being great. At the intersection of these circles is the target goal.

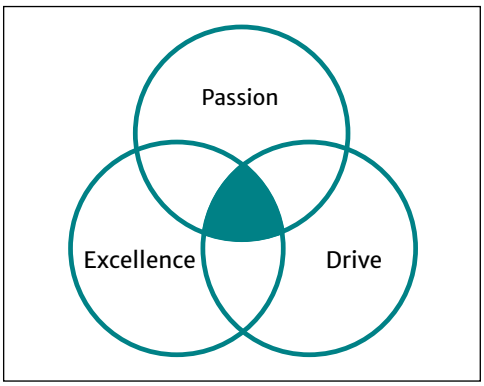


**Figure 1.** A depiction of the Hedgehog Concept. Adapted from The Jim Collins website.[3]

**AMWA:** ***How Can Writers Create Credibility When They Are New to a Team?***

**Carter:** To create credibility,

- be accountable,
- demonstrate technical acumen,
- give and earn respect,
- talk less and act more, and
- demonstrate commitment.

**AMWA:** ***How Can Writers Manage a Team Without Authority?***

**Carter:** Leading peers or more senior team members through document preparation requires writers to

- understand the team goals and motivators,
- set and document expectations at the project's start,
- be an empathetic listener,
- hold team members accountable through consistent follow-up,
- create positive visibility for team members, and
- master their emotional intelligence.

Remember that managers control and direct but that leaders influence and inspire.

**AMWA:** ***Do You Have an Example of a Pharmaceutical Company Hiring a CRO for Its Expertise but Then Not Using This Expertise? If So, How Do You Recommend Mitigating the Issue?***

**Carter:** Yes. In this example, a pharmaceutical company hires a CRO for its therapeutic expertise and experience with the Food and Drug Administration (FDA) Center for Drug Evaluation and Research Office of Rare Disease, Pediatrics, Urologic, and Reproductive Medicine. In their desperation to accelerate their New Drug Application (NDA) submission due to competitive pressures and their desire to be first to market, the company asks the CRO to write their summary of clinical safety and the integrated summary of safety with only 1 year of data, although FDA guidance suggests at least 2 years of pivotal safety data. This places the NDA at risk for rejection by the FDA.

To mitigate this issue, the CRO should transparently share its concerns and prior experience and ensure that communication reaches key stakeholders. Risks and mitigation strategies should be documented in meeting minutes. Finally, the CRO should stay motivated and demonstrate its technical expertise by delivering a quality document.

**AMWA:** ***Do You Have an Example of a Pharmaceutical Company and CRO Not Agreeing on a Timeline? If So, How Do You Recommend Mitigating the Issue?***

**Carter:** Yes. In this example, the pharmaceutical company and CRO agree in a contract that the Clinical Study Report (CSR) for a pivotal study will have 2 drafts and a final draft; however, the tables, listings, and figures (TLFs) will not be available until the final draft. This CSR is on the critical path for the NDA submission. Here, the issue becomes the late delivery of the TLFs, which leads to compressed timelines for delivery of the final CSR and a limited time for a full quality-control review. In this situation, the delays with the final draft are leading to a protracted review cycle with the introduction of new reviewers and new stakeholders.

Missing timelines or producing poor-quality deliverables can negatively impact long-term credibility and goodwill. To mitigate this issue, the writer, and project manager, if available, should assert themselves and push back. For example, they can advise the pharmaceutical company of the consequences of this shortened review cycle, and of changing reviewers and stakeholders. They should partner with the pharmaceutical company to negotiate a realistic timeline. To speed document development while the TLFs are not available, the writer should develop a shell CSR by using draft or placeholder data and seek approval by using the agreed upon template. In addition, the writer should identify quality risks and mitigation upfront (eg, using draft data). Finally, the writer should use online review technology (eg, PleaseReview) to facilitate authoring followed by comment-resolution meetings.

**AMWA:** ***Do You Recommend That Medical Writers Increase Their Project Management (PM) Skills? If So, What Skills or Concepts Are Important to Project Management?***

**Carter:** Yes. Upskilling your PM skills is critical to increasing your effectiveness as a medical writer. Pharmaceutical companies are increasingly expecting medical writers to take a leadership role within the submission team. PM is multifaceted and includes communication, teamwork, analysis, project planning, establishing a budget, establishing goals, understanding risks, problem solving, meeting deadlines, and reaching milestones.

Medical writers should be aware of 2 project management theories. In the first theory (Figure 2),[4] a project has 3 limitations: time, cost, and scope. Time refers to the project timeline, cost refers to the budget established for the project, and scope refers to the project purpose and requested deliverables.

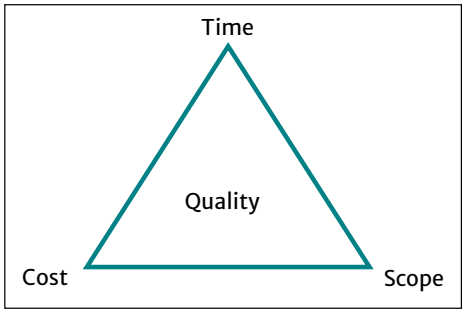


**Figure 2.** Project Management Theory 1. Adapted from the Skill Point website.[4]

A change in any one of these limitations will require an adjustment to the remaining limitations. For example, if the pharmaceutical company requires an expedited timeline, the cost of the project would increase as more writers are allocated to its completion. Additionally, quality is a key factor with this theory because changes to any of the limitations may affect the quality of the deliverable.

An updated version of this theory (Figure 3)[4] shows quality as a fourth limitation. Customer satisfaction becomes the key factor in this second theory, as a project's success is defined

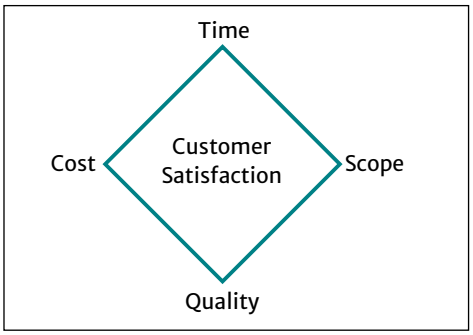


**Figure 3.** Project Management Theory 2. Adapted from the Skill Point website.[4]

by meeting or exceeding a customer's (pharmaceutical company's) expectations.

**AMWA:** ***Do You Have an Example of a Pharmaceutical Company Losing Confidence in a CRO? If So, What Advice Do You Have for the CRO to Regain the Pharmaceutical Company's Confidence?***

**Carter:** Yes. In this example, the pharmaceutical company and CRO have been in a long-term consulting relationship; however, the last few projects have not gone well, which has resulted in the projects being pulled back in house. Additionally, there have been changes in the internal leadership of the pharmaceutical company, which has led to a decline in outsourced projects to the CRO. Here, the issues include the negative feedback on recent projects and the relative anonymity of the CRO in terms of the new leadership at the pharmaceutical company.

Confidence can be lost overnight, and regaining confidence takes a significant amount of time. To mitigate this issue, the CRO should review the performance feedback and develop a corrective action plan, collaborate on the lessons learned, and take accountability. It can then offer some concessions to the pharmaceutical company, such as a lower rate or credit for future work. A cooling-off period may be necessary. In addition, successfully completing lower-complexity tasks may help reestablish credibility.

**AMWA:** ***Do You Have Any Proven Techniques for Transitioning a Business Relationship Toward a Partnership?***

**Carter:** Yes. To strengthen and transform the CRO–pharmaceutical company relationship into a strategic partnership, a CRO must build TRUST with the pharmaceutical company. TRUST is an outward expression of the value proposition a CRO brings to the partnership. The letters of this acronym represent the qualities the CRO must demonstrate:

- Technical competency—knowledge and skills to successfully complete the deliverable
- Reliability—trustworthiness and consistent performance
- Unity on purpose—understanding and alignment with the pharmaceutical company's goals
- Service orientation—priority being given to the pharmaceutical company's needs and excellent customer service
- Transparency—discussion of any issues and advice based on experience

**AMWA:** ***What Are the Key Takeaways for Transitioning From a Relationship to Partnership?***

**Carter:** For a CRO to transition from a transactional relationship to a strategic partnership with a pharmaceutical company, there are 3 takeaways:

- manage projects effectively,
- create and deliver on the UVP, and
- establish value through TRUST.

***Author declaration and disclosures:*** *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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